

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

21415-0013

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

10/521,571

INTERNATIONAL APPLICATION NO.

PCT/AU03/000919

INTERNATIONAL FILING DATE

July 17, 2003

PRIORITY DATE CLAIMED

July 17, 2002

TITLE OF INVENTION

TRANSCRIPTIONAL CONTROL ELEMENT, CHIMERIC CONSTRUCTS AND USES THEREFOR

APPLICANT(S) FOR DO/EO/US

James Langham DALE; Robert Maxwell HARDING; Douglas Kenneth BECKER; Gregory John HAFNER; Ilin YANG

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ had been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included
13. ☐ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or address letter.
17. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 132 and 37 CFR 1.821-1825
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4)
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: **copy of Notification of Defective Response (dated 2/18/06)**

|  |  |   |  |   |  |
|--|--|---|--|---|--|
| U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.7)<br><b>10/521,571</b> |  | INTERNATIONAL APPLICATION NO.<br><b>PCT/AU03/000919</b> |  | ATTORNEY'S DOCKET NUMBER<br><b>21415-0013</b> |  |
|--|--|---|--|---|--|

|  |              |   |            |  |    |
|--|--------------|---|------------|--|----|
| 21. The following fees are submitted:<br><input type="checkbox"/> a) Basic national fee.....\$300.00<br><input type="checkbox"/> b) Examination fee .....\$200.00<br><input type="checkbox"/> c) Search fee.....\$500.00<br><br><div style="text-align: right;"><b>TOTAL OF ABOVE CALCULATIONS =</b></div> |              |   |            | <b>CALCULATIONS PTO USE ONLY</b><br><br><br> |    |
| <input checked="" type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.                      |              |   |            |  |    |
| TOTAL SHEETS   | EXTRA SHEETS | NUMBER EXTRA (of each additional 50 or fraction thereof rounded up to a whole number) | RATE       |  |    |
| 100-100 =  | /50 =        |   | x \$250.00 |  |    |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).   |              |   |            |  |    |
| CLAIMS   | NUMBER FILED | NUMBER EXTRA  | RATE       |  |    |
| Total claims   | - 20 =       |   | x \$50.00  |  |    |
| Independent claims   | - 3 =        |   | x \$200.00 |  |    |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)  |              |   | +          | \$360.00                                     |    |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |              |   |            |  |    |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.   |              |   |            |  |    |
| <b>SUBTOTAL =</b>  |              |   |            |  |    |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).  |              |   |            | +  |    |
| <b>TOTAL NATIONAL FEE =</b>  |              |   |            |  |    |
| Fee for recording the enclose assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property  |              |   |            | +  |    |
| <b>TOTAL FEES ENCLOSED =</b>   |              |   |            | <b>\$0 fees due</b>                          |    |
|  |              |   |            | <b>Amount to be refunded:</b>                | \$ |
|  |              |   |            | <b>Amount to be charged:</b>                 | \$ |

a. ☐ A check in the amount of \_\_\_\_\_ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.

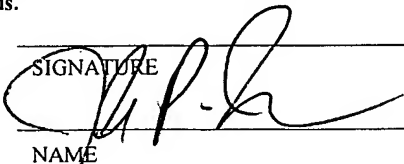
c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment  
To Deposit Account No. **08-1641** A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

**HELLER EHRMAN LLP**  
 1717 Rhode Island Avenue, N.W.  
 Washington, D.C. 20036  
 Customer No. : 26633

SIGNATURE  
  
 NAME  
**John P. Isacson**  
 REGISTRATION NUMBER  
**33,715**

3-8-06

Date

08 MAR 2006



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|-----------------------------|-----------------------|------------------|
| 10/521,571                  | James Langham Dale    | 21415-0013       |

INTERNATIONAL APPLICATION NO.

PCT/AU03/00919

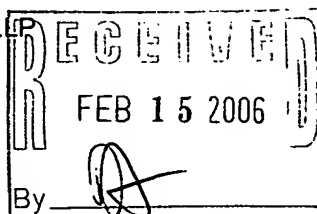
| I.A. FILING DATE | PRIORITY DATE |
|------------------|---------------|
|------------------|---------------|

07/17/2003

07/17/2002

26633

HELLER EHRMAN WHITE & MCAULIFFE LLP  
 1717 RHODE ISLAND AVE, NW  
 WASHINGTON, DC 20036-3001



CONFIRMATION NO. 4029

371 FORMALITIES LETTER



\*OC000000018038868\*

Date Mailed: 02/13/2006

## NOTIFICATION OF DEFECTIVE RESPONSE

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495)

- Indication of Small Entity Status
- Priority Document
- Copy of the International Application filed on 01/18/2005
- Copy of the International Search Report filed on 01/18/2005
- Copy of IPE Report filed on 01/18/2005
- Copy of Annexes to the IPER filed on 01/18/2005
- Preliminary Amendments filed on 01/18/2005
- Information Disclosure Statements filed on 09/19/2005
- Biochemical Sequence Diskette filed on 08/04/2005
- Oath or Declaration filed on 05/16/2005
- Biochemical Sequence Listing filed on 08/04/2005
- Small Entity Statement filed on 04/18/2005
- U.S. Basic National Fees filed on 08/04/2005
- Assignment filed on 05/16/2005
- Priority Documents filed on 01/18/2005
- Power of Attorney filed on 05/16/2005
- Specification filed on 01/18/2005
- Claims filed on 01/18/2005
- Drawings filed on 01/18/2005

Applicant's response filed 09/19/2005 is hereby acknowledged. The following requirements set forth in the NOTIFICATION of MISSING REQUIREMENTS mailed 06/08/2005 have not been completed.

- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper

or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

**Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR 1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).**

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- For Rules Interpretation, call (571) 272-0951
- For Patent Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patent Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

BARBARA A CAMPBELL

Telephone: (703) 308-9140 EXT 217

**PART 1 - ATTORNEY/APPLICANT COPY**

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/521,571                  | PCT/AU03/00919                | 21415-0013       |

**STIC Biotechnology Systems Branch**

**RAW SEQUENCE LISTING**  
**ERROR REPORT**

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/521,571  
Source: PCT/10  
Date Processed by STIC: 1/9/06

**THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.**

**PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:**

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

**FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221**

**TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.2.2 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:**

**<http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm>**

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):  
U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/24/05



PCT

## RAW SEQUENCE LISTING

DATE: 01/09/2006

PATENT APPLICATION: US/10/521,571

TIME: 11:20:18

Input Set : A:\21415-0013.txt

Output Set: N:\CRF4\01092006\J521571.raw

3 &lt;110&gt; APPLICANT: Dale, James Langham

4 Harding, Robert Maxwell

5 Becker, Douglas Keith

6 Hafner, Gregory John

7 Yang, Ilin

9 &lt;120&gt; TITLE OF INVENTION: Transcriptional Control Element, Chimeric Constructs and

Uses

10 Therefor

12 &lt;130&gt; FILE REFERENCE: 21415-0013

14 &lt;140&gt; CURRENT APPLICATION NUMBER: 10/521,571

15 &lt;141&gt; CURRENT FILING DATE: 2005-01-18

17 &lt;150&gt; PRIOR APPLICATION NUMBER: PCT/AU2003/000919

18 &lt;151&gt; PRIOR FILING DATE: 2003-07-17

20 &lt;150&gt; PRIOR APPLICATION NUMBER: USSN 60/396,912

21 &lt;151&gt; PRIOR FILING DATE: 2002-07-17

23 &lt;160&gt; NUMBER OF SEQ ID NOS: 29

25 &lt;170&gt; SOFTWARE: PatentIn version 3.2

**Does Not Comply  
Corrected Diskette Needed**

## ERRORED SEQUENCES

1475 &lt;210&gt; SEQ ID NO: 29

1476 &lt;211&gt; LENGTH: 12

1477 &lt;212&gt; TYPE: DNA

1478 &lt;213&gt; ORGANISM: Artificial Sequence

1480 &lt;220&gt; FEATURE:

1481 &lt;223&gt; OTHER INFORMATION: GUS2 primer

1483 &lt;400&gt; SEQUENCE: 29

1484 ttacttggtt gc

12

E--&gt; 1490 27

E--&gt; 1491 27

E--&gt; 1496 1

*delete*

*see p. 2 for more errors*

10/521,571 2

<210> 10  
 <211> 20  
 <212> DNA  
 <213> Artificial Sequence

<220>  
 <223> Badna FP primer

<220>  
 <221> modified base  
 <222> (5) .. (6)  
 <223> I

<220>  
 <221> modified base  
 <222> (10) .. (11)  
 <223> I

<220>  
 <221> modified base  
 <222> (18) .. (19)  
 <223> I

<400> 10  
 atgccttygg@araaygcc

"C" and "T" can only represent themselves,  
 nothing else

"G" and "A" can only  
 represent themselves

"C" can only  
 represent itself

If these nucleotides can also represent  
 Inosine, use "N" instead, and explain  
 in <2207-2237> section.

20

FYI: Inosine cannot be shown in a sequence  
 as "i"; it can only be shown as "N", with  
 an explanation in <2207-2237> section.

same error in sequence !!

VERIFICATION SUMMARY

PATENT APPLICATION: US/10/521,571

DATE: 01/09/2006

TIME: 11:20:19

Input Set : A:\21415-0013.txt

Output Set: N:\CRF4\01092006\J521571.raw

L:1490 M:254 E: No. of Bases conflict, this line has no nucleotides.

L:1493 M:254 E: No. of Bases conflict, this line has no nucleotides.

L:1496 M:254 E: No. of Bases conflict, this line has no nucleotides.